K082812

Non-Confidential Summary of Safety and Effectiveness

23-Sep-08

OCT 22 2008

Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015

Tel – 847-247-5609
Fax – 847-680-6269

Official Contact: Randy Kellogg – VP Marketing & Product Development

Proprietary or Trade Name: HBP-2070

Common/Usual Name: Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Classification Name/Code: DXN – System, Measurement, Blood-pressure, Non-invasive

Device: Model – HBP-2070

Predicate Devices: Omron – Press-Mate Advantage – K973637

Device Description:
The proposed vital signs monitor is a modification of a previously cleared Colin Press Mate Advantage (K973637).

The proposed model, HBP-2070, measures and monitors:

- Noninvasive blood pressure (NIBP)
- Oxygen saturation (SpO2)
- ECG
- Respiration rate (RR)
- Heart Rate (HR), and
- Temperature

Indications for Use:
The HBP-2070 is intended to be used to monitor electrocardiography (ECG),heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressure) (NIBP), functional arterial oxygen saturation (SpO_2), pulse rate (PR), respiration (RR) temperature (Temp) for adult, pediatric, and neonatal patients in all areas of a hospital and hospital-type facilities.

Monitor users should be skilled at the level of a technician, doctor, nurse, or medical specialist.

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Patient Population: Adult, Pediatric, Neonate

Environment of Use: All areas of a hospital and hospital-type facilities

Contraindications: None

Summary of substantial equivalence

Indications for Use	Monitors: Non-invasive blood pressure (NIBP), Oxygen saturation(SpO2), ECG, Respiration rate, Heart rate (HR), and Body Temperature (Temp)	same as predicate device
Patient Population	Adult, Pediatric or Neonatal	
Environment of use	All areas of a hospital and hospital-type facilities	

Physical Characteristics		
Dimensions (mm)	172 (W) × 216 (D) × 228 (H) mm	257 (W) × 210 (D) × 152 (H) mm
Weight	Approximately 6.0kg (including internal battery)	Approximately 3.5kg (including internal battery)
Environmental Condition		
Operating conditions	0 to 40 °C, 30 to 85 %RH non-condensing	5 to 40 °C, 30 to 85 %RH non-condensing
Storage conditions	-20 to 70 °C, 10 to 100 %RH non-condensing	-20 to 60 °C, 10 to 95 %RH non-condensing
Display		
Screen size	5.6inch TFT color LCD	7inch TFT color LCD
Resolution	400 × 320 pixel	800 × 480 pixel
Number of Traces	1 or 2 waveforms	1 or 3 waveforms
Electrical		
Power source	AC Mains Battery (lead acid)	AC Mains Battery (Lithium ion)
Power range	AC: 100-120V 50 / 60Hz Battery: 12V 1.8Ah	AC: 100-240V 50 / 60Hz Battery: 11.1V 2.4Ah or 7.2Ah
Battery operation time	A battery typically provides operating time of 30 minutes when fully charged with no printing, no external communication, no audible alarm sound and one NIBP measurement per 5 minutes at 25°C.	A battery typically provides operating time of 1 hour and 6 hour when fully charged with no printing, no external communication, no audible alarm sound and one NIBP measurement per 10 minutes at 25°C.

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	Predicate Press-Mate Advantage K973637	**New Model HBP-2070 series**
Recorder		
Type	Thermal	same as predicate device
Resolution	8 dot/min	same as predicate device
Number of Channel	1 to 2 channels	same as predicate device
Paper width	58 mm	50 mm
Paper speed	6.25,25 and 50mm/sec	25 and 50mm/sec
【NIBP】		
Measurement method	Oscillometric method	same as predicate device
Patient target	Adult, Pediatric, Neonatal	same as predicate device
NIBP	SYS - Adult) 60 – 250 mmHg	same as predicate device
Measurement range	Pediatric / Neonatal) 40 – 120 mmHg MAP - Adult) 45 – 235 mmHg Pediatric / Neonatal) 30 -100 mmHg DIA - Adult) 40 – 200 mmHg Pediatric / Neonatal) 20 -90 mmHg	Uses another NIBP module – M3500 which has been used in our predicate HBP-T105 (K071645)
Pressure display range	10 – 300 mmHg	0-300mmHg (Adult) 0-150mmHg(Neo)
Accuracy of pressure indicator	Within ±3 mmHg or 1 % of reading	Within ±3 mmHg
Pressure sensor	Semiconductor pressure sensor	same as predicate device
Pulse rate range	Pulse rate: 40 to 240 beats/min.	same as predicate device
Accuracy of pulse rate	Within ±2 beats/min or ±2% of reading	same as predicate device
Inflation method	DC Rolling diaphragm pump	same as predicate device
Deflation method	Dynamic linear deflation	same as predicate device
Shock protection	Type BF(Defibrillator protected)	Type CF(Defibrillator protected)
【ECG】		
HR measure range	30 - 300 BPM	30 - 300BPM
HR Accuracy	±3 BPM or ±5% whichever is greater	±1 BPM or ±1% whichever is greater
Lead	3 / 5 Lead Lead[illegible],aVR,aVL,aVF,V(Chest)	same as predicate device
Lead off detection	Detected and displayed	same as predicate device
Input dynamic range	±5mV AC,±300mV DC	same as predicate device
Voltage range	±0.5mV ~ ±5mV	same as predicate device
Signal Width	40 ms ~ 120 ms (Q to S)	same as predicate device
Frequency response		
Low Extend	0.05 Hz - 40 Hz	same as predicate device
Filter	None	0.5 Hz - 30 Hz
Monitor	0.32 Hz - 40 Hz	0.5 Hz - 40 Hz
Respiration rejection	None	1 Hz - 40 Hz
ECG size	×1/2,×1,×2,×4	×1/4,×1/2,×1,×1.5,×2
Display Sweep Size	6.25,12.5,25 mm/sec	12.5,25,50 mm/sec
Shock protection	Type CF(Defibrillator protected)	same as predicate device

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	Predicate Press-Mate Advantage K973637	**New Model HBP-2070 series**
【RESP】		
Measurement method	Trans-thoracic impedance	same as predicate device
Range	3 to 150 breaths/min	3 to 120 breaths/min
Accuracy of pulse rate	±3 breaths/min	same as predicate device
Lead	RA to LL	RA to LA
Display Sweep Size	6.25, 12.5, 25 mm/sec	same as predicate device
Shock protection	Type CF(Defibrillator protected)	same as predicate device
【SpO2】		
SpO2 module	Nellcor MP-203	Nellcor NELL-3 Predicate Omron BP-S510 (K063690)
Measurement method	2 wave length pulse wave type	same as predicate device
SpO2 display range	50 - 100 %	1 - 100 %
Accuracy	Adult - 70% - 100% ±2digits 1% - 69% unspecified Pediatric / Neonate 70% - 100% ±3digits 1% - 69% unspecified	same as predicate device
Display Sweep Size	12.5,25,50 mm/sec	same as predicate device
Pulse rate display range	20 - 250 beats/min	same as predicate device
Accuracy of pulse rate	Within ±3 beats/min	same as predicate device
Shock protection	Type BF(Defibrillator protected)	Type CF(Defibrillator protected)
【TEMP】		
Measurement method	Thermistor probe YSI 400 or 700	same as predicate device
Parameter Displayed	Temp (1ch)	T1 (1ch)
display range	15.0 - 45.0°C	same as predicate device
Accuracy	±0.1 °C (25 °C to 45 °C) ±0.2 °C (15 °C to less than 25 °C)	±0.1 °C
Scale	Selectable from C to F	same as predicate device
Probe Accuracy	±0.1 °C	same as predicate device
Shock protection	Type BF(Defibrillator protected)	Type CF(Defibrillator protected)

The base modifications are:

- Change in the SpO2 module to Nell 3 which has been used and cleared in our predicate BPS S510 (K063690)
- Change in the NIBP module to M3500 which has been used in our predicate HBP- T105 (K071645).
- Software updates

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Differences Between Other Legally Marketed Predicate Devices

The Omron HBP-2070 vital signs monitor is viewed as substantially equivalent to the predicate device because:

Indications –
- Identical to predicate – K973637

Technology –
- Identical algorithms to predicate – K071645

Materials –
- The materials in patient contact are identical to predicate devices as listed in **Section 15.**

Environment of Use –
- Identical to predicate – K973637

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2008

Omron Healthcare, Inc.
c/o Mr. Paul Dryden
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134-2958

Re: K082812
Trade/Device Name: Model HBP-2070
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Codes: MWI, DXN, DQA, FLL
Dated: September 23, 2008
Received: September 24, 2008

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082812 (To be assigned)

Device Name: HBP-2070

Indications for Use:

The HBP-2070 is intended to be used to monitor electrocardiography (ECG),heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressure) (NIBP), functional arterial oxygen saturation (SpO_2), pulse rate (PR), respiration (RR) temperature (Temp) for adult, pediatric, and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse, or medical specialist.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Roy Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082812